

# **EXHIBIT A**

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CA03-2401

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

TORPHARM, INC.,	)	
	)	
Plaintiff,	)	Docket No. CA 03-2401
	)	
v.	)	
	)	
FDA,	)	Washington, D.C.
	)	Friday, January 2, 2004
Defendant.	)	

TRANSCRIPT OF PRELIMINARY INJUNCTION HEARING  
BEFORE THE HONORABLE RICHARD W. ROBERTS  
UNITED STATES DISTRICT JUDGE

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<p style="text-align: right;">Page 2</p> <p>APPEARANCES: Cont  Intervening FROMMER, LAWRENCE &amp; HAUG, LLP  Defendant: Charles J. Raubicheck, Esq.  (Alphapharm) 745 Fifth Avenue  New York, NY 10151  212.588.0800  Court Reporter: Scott L. Wallace, RDR, CRR  Official Court Reporter  Room 6814, U.S. Courthouse  Washington, D.C. 20001  202.326.0566</p> <p>Proceedings reported by machine shorthand, transcript produced  by computer-aided transcription</p> <p style="text-align: right;">Scott L. Wallace, RDR, CRR  Official Court Reporter</p>	<p style="text-align: right;">Page 4</p> <p>1 MS. MAZZOCHI: And would you like me to proceed or do you  2 need to have defense --  3 THE COURT: Well, you can introduce yourself just for the  4 record.  5 MS. MAZZOCHI: That's fine. My name is Deanne Mazzochi  6 and I'm an attorney with Lord, Bissell &amp; Brook in Chicago, acting  7 on behalf of Torpharm.  8 THE COURT: Very well.  9 MR. STEARN: Good afternoon, Your Honor. My name is  10 Douglas Stearn. I'm here with the Department of Justice on  11 behalf of the federal defendants, the Food and Drug  12 Administration, Secretary Thompson and Commissioner McClellan.  13 With me is Marc Caden with the Office of Chief Counsel at  14 FDA.  15 THE COURT: All right, good afternoon.  16 MR. RAUBICHECK: And excuse me, Your Honor. My name is  17 Charles Raubicheck. I'm with the firm of Frommer, Lawrence &amp;  18 Haug, representing the intervening defendant, Alphapharm, Pty,  19 Limited.  20 THE COURT: All right. Good afternoon to all of you.  21 I want to take up first the suggestion in the papers that  22 this matter be treated as summary judgment papers or the  23 preliminary injunction hearing be consolidated on the merits  24 under Rule 65.  25 I've looked at the papers and I have not found any genuine</p>
<p style="text-align: right;">Page 3</p> <p>1 PROCEEDINGS  2 THE DEPUTY CLERK: This is civil action 03-2401, Torpharm,  3 Inc. versus FDA; intervening defendant, Alphapharm.  4 Counsel, would you kindly step up to the podium and  5 introduce yourself to the judge.  6 MR. TSIEH: Good afternoon, Your Honor. Arthur Tsien from  7 Olsson, Frank and Weeda for Plaintiff Torpharm.  8 Torpharm would like Deanne Mazzochi from Lord, Bissell &amp;  9 Brook in Chicago to represent it here today. Your Honor granted  10 her motion to appear pro hac vice on a provisional basis  11 Wednesday. We cured a defect by submitting a supplemental  12 declaration Wednesday.  13 THE COURT: All right. I'm not sure that I've seen it,  14 but I will trust that you added the number of times, I think,  15 that was missing?  16 MR. TSIEH: I would be pleased to hand up a copy, Your  17 Honor.  18 THE COURT: All right. Well, just tell me what the number  19 was. Was there a number?  20 MS. MAZZOCHI: It was zero, in fact.  21 THE COURT: Zero times. Well, I will convert my  22 provisional ruling to a final ruling. You are admitted pro hac  23 vice and welcome to the Court.  24 MS. MAZZOCHI: Thank you, Your Honor.  25 THE COURT: All right.</p>	<p style="text-align: right;">Page 5</p> <p>1 dispute in your papers about material facts, so I do propose to  2 proceed that way unless there is some objection to that.  3 Now, with respect to argument, what if I give each side  4 roughly a half hour? Now, maybe the FDA and Alphapharm might  5 want to divide that up any way you want to; Torpharm, if you want  6 to reserve some of your time for rebuttal, you can do that.  7 But had you all discussed some alternative way of  8 proceeding or some alternative schedule? If not, why don't we  9 just proceed in that fashion and invite Torpharm to go first.  10 MS. MAZZOCHI: Thank you, Your Honor. If I may, I would  11 like to reserve approximately ten minutes of rebuttal time.  12 THE COURT: All right.  13 MS. MAZZOCHI: And just to begin, I would like to thank  14 the Court very much for taking the time to hear us today. We  15 understand with the holidays and the urgency involved, that  16 additional efforts are required.  17 As this Court is aware, this case involves 180-day  18 exclusivity periods under the Hatch-Waxman Act, which the D.C.  19 Circuit has recognized in <i>Mova v. Shalala</i> is a very powerful  20 incentive for generic companies to invite patent challenges years  21 before market entry is possible.  22 There's no dispute here amongst the parties that Torpharm  23 is, in fact, the first ANDA applicant to file an ANDA with a  24 paragraph IV certification.  25 THE COURT REPORTER: Slow down just a little bit.</p>

2 (Pages 2 to 5)

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1 MS. MAZZOCHI: Sure. I apologize.  
2 Torpharm is the first ANDA applicant to submit to FDA an  
3 ANDA which contained a paragraph IV certification for the patent  
4 that was then listed in the FDA publication known as the Orange  
5 Book, U.S. patent number 4,721,723.

6 And our understanding is that as of tomorrow, FDA is  
7 planning to deny Torpharm its exclusivity rights as a result of  
8 that filing, and that —

9 THE COURT: You mean sole exclusivity rights?

10 MS. MAZZOCHI: Sole exclusivity rights.

11 And that FDA is in fact planning on awarding a shared  
12 exclusivity right to Alphapharm. We believe that this denial of  
13 Torpharm's ability to fully exploit its 180-day exclusivity  
14 period represents arbitrary and capricious agency action for  
15 several reasons.

16 First, we believe that the statute on its face creates a  
17 sole exclusivity right by requiring FDA to delay approval of  
18 rival ANDAs until the expiration of 180 days after certain  
19 triggering events in the statute, which everyone agrees here was  
20 Torpharm's first commercial marketing date, which was  
21 September 8th of 2003.

22 180 days from that period would be approximately March 6th  
23 of 2004.

24 THE COURT: Did you say that was the first commercial  
25 marketing date or the date on which the secretary is notified of

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1 way in which it can reconcile conducting a patent-by-patent  
2 approach to exclusivity with the statute, we believe that, at the  
3 very least, ensuring that the first 180-day exclusivity period is  
4 not devalued by nature of having to be shared amongst one or, I  
5 believe here for Paroxetine, there are now over ten ANDA  
6 applicants who have gotten ANDA applications on file, the  
7 cascading approach would allow you to, at the very least, keep  
8 the first ANDA applicant's exclusivity period fully in place and  
9 would allow the first applicant to fully enjoy the fruits of  
10 their litigation labors, if you will.

11 And if FDA truly believes that there are policy advantages  
12 to taking the patent-by-patent based approach, which would  
13 encourage other generic applicants to challenge late-listed  
14 patents, we believe that having the cascading approach would,  
15 again, ensure that you've got some type of incentive that is  
16 fixed, that is readily discernible and that can actually be  
17 counted on in terms of proceeding forward with litigation and,  
18 you know, up front making the decision as to whether it's even  
19 worth the time to submit a paragraph IV certification in the  
20 first instance.

21 THE COURT: Well, would you concede that I can't even  
22 reach the question about cascading exclusivity until and unless I  
23 decide that the statute is ambiguous? And if there is some  
24 ambiguity, then we have to march into whether the FDA's  
25 interpretation of it was permissible and reasonable?

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1 the first commercial marketing?

2 MS. MAZZOCHI: It was — we believe that the notice did,  
3 in fact, occur simultaneously, so there may be a day or two  
4 leeway one way or the other. But I believe the parties are in  
5 agreement that the end of the exclusivity period comes at about  
6 March 6th of 2004.

7 Nowhere in the statute does it set forth any type of  
8 regime where exclusivity can be shared simultaneously amongst  
9 ANDA applicants. FDA has invented this concept in a series of  
10 ad hoc letter rulings against a background of administrative  
11 positions which have involved several flip flops as to what FDA  
12 considers to be an appropriate way to award and consider who has  
13 entitlement to 180-day exclusivity periods.

14 THE COURT: Well, forgive me for interrupting. Can I ask  
15 you two questions on that argument?

16 MS. MAZZOCHI: Sure.

17 THE COURT: How does that argument support your advancing  
18 the argument that this cascading or rolling exclusivity may be an  
19 appropriate interpretation of the statute where the statute has  
20 no such reference to that either?

21 MS. MAZZOCHI: We — FDA has taken the position that the  
22 statute authorizes it to analyze exclusivity on a, quote/unquote,  
23 patent-by-patent basis. We obviously believe that the  
24 one-first-applicant approach is the correct approach. However,  
25 if there is some perception that FDA believes there needs to be a

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1 MS. MAZZOCHI: I think that — Torpharm believes that what  
2 the statute requires is that there be one ANDA applicant, notably  
3 the first filer, who fully enjoys their 180-day exclusivity  
4 period.

5 As to which approach is deemed the most proper one by the  
6 Court, we are willing to leave that to the Court to decide. We  
7 believe that the first applicant approach is the correct one, but  
8 under either approach, Torpharm still comes out of this with its  
9 180-day exclusivity period intact and FDA still cannot approve  
10 Alphapharm's ANDA until after — on or after about March 6th,  
11 2004.

12 THE COURT: Well, that answers the result. I was asking  
13 about process. I take it you don't disagree that, absent the  
14 language in the statute about cascading, I'd have to find some  
15 ambiguity that would allow me to go in and then determine whether  
16 the FDA's interpretation was permissible or reasonable?

17 MS. MAZZOCHI: I believe that the statute discusses having  
18 a previous application and we believe that that previous  
19 application refers to a first ANDA applicant. You can still have  
20 a first ANDA applicant under the cascading approach as well.

21 The question is whether you're going to give — you're  
22 going to consider subsequent applicants who are filing a newly  
23 listed patent to constitute a new ANDA application that has a  
24 paragraph IV certification for which there was no prior paragraph  
25 IV certification as to that same patent.

3 (Pages 6 to 9)

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1 We disagree that FDA should -- how do I put this the right  
2 way?

3 We believe that the statute only allows -- allows for one  
4 applicant to have a full 180-day exclusivity period. Whether a  
5 later applicant can have an additional exclusivity period by  
6 virtue of the nature of the filing that they're making -- if in  
7 fact a patent-by-patent approach is imported into that part of  
8 the analysis -- that that's sort of a step two to the analysis.

9 I think that no matter what, the ANDA applicant who is the  
10 first filer gets their 180-day exclusivity period. Then the  
11 question becomes: Do you want to say that a later-in-time  
12 applicant can get a 180-day exclusivity period of their own?

13 But what the statute does not allow for is that the  
14 180-day exclusivity period can be split simultaneously and shared  
15 by multiple applicants. That is the point that Torpharm says is  
16 nowhere found in the statute.

17 THE COURT: I was just wondering: When you mention the  
18 FDA's flip flops, is your current argument somewhat of a flip  
19 flop for Torpharm? Hasn't Torpharm argued something differently  
20 in another case?

21 MS. MAZZOCHI: That might be the case if we'd actually  
22 been prevailing on those cases, Your Honor.

23 THE COURT: Go ahead. I didn't mean to prolong it on that  
24 point.

25 MS. MAZZOCHI: Oh, no, that's fine.

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1 One thing that, with respect to FDA's flip flopping, FDA  
2 has in fact indicated that the first filer approach is one that  
3 is supported by the statute.

4 To the extent FDA has engaged in these series of letter  
5 rulings, the methodology that they are putting forth and the  
6 results that they are obtaining, that in and of itself, prior to  
7 their decision here, was never the subject of notice and comment  
8 rule making. And we believe that it's because of that, because  
9 there is no set standard, that we're starting to lead to the  
10 arbitrary and capricious results that we're seeing here.

11 Ultimately, Torpharm's position is that, under the first  
12 filer approach, this Court should enjoin any other ANDA approval  
13 that's going to encroach on Torpharm's unfettered exclusivity.  
14 And, you know, the result is going to be the same, irrespective  
15 of which approach, whether it's the cascading approach or the  
16 first filer approach.

17 Now the question becomes: What happens if you were to  
18 accept FDA's approach? And for the reasons stated in our briefs,  
19 we obviously do not believe that FDA's approach here is the  
20 correct one.

21 But we don't believe that even under FDA's current  
22 rulings, that FDA is allowed to give multiple exclusivity rights  
23 to multiple ANDA applicants, particularly Alphapharm here. The  
24 reason why is because of the specific nature of the -- or the  
25 identity of the patent, which we discovered after we finally

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1 received the administrative record from FDA.

2 And as we raised in our reply briefs, FDA is basing its  
3 decision to award a shared exclusivity to Alphapharm, based on  
4 Alphapharm's alleged first filer status in connection with the  
5 '449 patent. And that's the only patent that FDA is using to, if  
6 you will, invite Alphapharm to share in the exclusivity table.

7 In our reply brief, we explain why the '449 patent is a  
8 fairly unique patent here in view of the additional patents that  
9 have been listed in the Orange Book, because the '449 patent --  
10 it's actually not a GSK patent.

11 The '449 patent is a patent that relates to a method of  
12 using Paroxetine -- I believe it's PMS -- to alleviate symptoms.  
13 That patent was listed; Alphapharm managed to -- or FDA asserts  
14 that Alphapharm certified to it. And FDA has taken the position  
15 that there are -- there is an additional first filer who has  
16 certified to that patent.

17 FDA has also taken the position that Alphapharm's  
18 activities with respect to the '449 patent can be used somehow to  
19 block Torpharm's ability to enjoy its 180-day exclusivity period.

20 We have two problems with this. First, under the existing  
21 regulations, Torpharm did not have to certify to the '449 patent.  
22 The reason why is because this patent was late-listed after 30  
23 days, after our ANDA was already on file. So as a result, under  
24 FDA's regulations, for the reasons I believe we explained in  
25 greater detail in our reply brief, we did not have to certify to

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1 the '449 patent.

2 Now, FDA's entire shared exclusivity regime arose out of  
3 the concept that you are going to have ANDA applicants who are  
4 going to be going head to head, mutually blocking one another,  
5 such that no one would ever be able to get on the market absent  
6 some type of shared exclusivity. And I believe they first  
7 started this with the Cisplatin letter.

8 The problem here is that Alphapharm is not blocking  
9 Torpharm's ability to enter the market because, even if you  
10 wanted to interpret the statute the way that FDA is suggesting  
11 that it be read, by saying that Alphapharm, by being the first  
12 filer on the '449 patent, is able to gain some type of  
13 exclusivity rights, that can -- you can only have the 180-day  
14 blocking scenario if Alphapharm is keeping Torpharm from entering  
15 the market by virtue of the '449 patent. But since Torpharm  
16 hasn't certified to the '449, there is no mutual blocking  
17 scenario.

18 Now, FDA is trying to take its ad hoc rulings one step  
19 further and saying, well, Torpharm, because you are blocked by  
20 Geneva on some other patents and Geneva is blocked by you on some  
21 other patents, we're going to let Alphapharm take advantage of  
22 the fact that Geneva -- and I believe they're referred to as  
23 Company X in FDA's brief -- we're going to allow Alphapharm to  
24 take advantage of Geneva's ability to block you in order to block  
25 you; and now that you're blocked, you have to share with

4 (Pages 10 to 13)

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1 Alphapharm.  
 2 We believe that this type of interpretation is starting to  
 3 get so far afield and attenuated that this, too, amounts to  
 4 arbitrary and capricious agency action. Making matters worse,  
 5 the -- to the extent Alphapharm was, in fact, a first filer in  
 6 connection with the '449 patent, it was only on a narrow number  
 7 of dosages, not even the full number of approved doses.  
 8 It's not clear to us whether FDA is planning on giving  
 9 Alphapharm full approval for all of the dosage ranges, which  
 10 include 10, 20, 30, and 40 milligram doses, but here Alphapharm  
 11 only has a first filer status on the 10, 20, and 30 milligram  
 12 doses. The other company, Company Y, which we believe to be  
 13 Zenith Pharmaceuticals, was apparently first on this 40 milligram  
 14 tablet.  
 15 So now we have the situation where Apotex is going to be  
 16 required to share the entire Paroxetine market with Alphapharm  
 17 when Alphapharm didn't even make it to the patent office first on  
 18 all of the available doses; Alphapharm isn't even blocking  
 19 Torpharm directly. And the FDA says well, but that's still okay  
 20 because Alphapharm is blocking Geneva, Geneva is blocking you, so  
 21 we're going to let you all share.  
 22 Well, the problem that we have with that is -- and again,  
 23 this is based on -- this is information that we didn't find out  
 24 until FDA's submission of the surreply brief and Alphapharm's  
 25 submission of their surreply brief.

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1 to get underneath the certification itself and challenge it. And  
 2 you know, they're going to say something about that. I imagine  
 3 there may be a response to that.  
 4 The fact is that this is their motion and it's their  
 5 burden; it's their burden to bring forth facts. They did not, in  
 6 their citizen petition, bring forth -- base their challenge on  
 7 this fact, just as they didn't in their initial papers.  
 8 Now, if they want to continue -- now, if the Court reaches  
 9 that fact, then, you know, perhaps there could be additional  
 10 litigation about it. But there's no basis for accepting this in  
 11 terms of a preliminary injunction motion.  
 12 Further, Your Honor, we put forth in the record the fact  
 13 there have been other first filers; we put forth the letters that  
 14 were sent. Now, they've been redacted because it's contrary to  
 15 FDA regulation to have the names put forth, but we've put forth  
 16 the letters to those other first filers, showing that they've  
 17 established first filer status on those other patents.  
 18 And really, what we're getting now is we're trying to get  
 19 more digging into the underlying facts and there is just no basis  
 20 for it at this 11th hour.  
 21 THE COURT: I'll reserve ruling on the motion for leave to  
 22 file, but you can continue.  
 23 I'm sorry. You're welcome to --  
 24 MR. RAUBICHECK: Your Honor, on behalf of Alphapharm, I  
 25 would also like to oppose this --

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1 The problem with all of this is that if Geneva is the  
 2 company who is being relied upon by FDA to try to block  
 3 Torpharm -- or, you know, by proxy, Alphapharm, via Geneva, is  
 4 used to block Torpharm -- based on the current administrative  
 5 record, Geneva didn't actually perfect their notice of a  
 6 paragraph IV certification for the '449 patent itself.  
 7 And we submitted to the Court today, and I believe we have  
 8 an additional copy for the Court if you would like it, explaining  
 9 this in a bit more detail. And we would ask that the Court  
 10 accept it because we do think that it helps to explain the  
 11 nuances of this, but --  
 12 THE COURT: Well, on that point, let me just ask if there  
 13 is any objection to accepting this --  
 14 MS. MAZZOCHI: I'm sure there will be.  
 15 THE COURT: -- filing today, the motion for leave to file  
 16 response to the surreply?  
 17 MR. STEARN: We would object, Your Honor. I got this  
 18 motion literally as I walked into court today. And further, Your  
 19 Honor, we really don't think -- this is just going to keep this  
 20 thing going because, you know, from our perspective, Your  
 21 Honor --  
 22 THE COURT: Let me invite you up to the microphone.  
 23 MR. STEARN: Sure, Your Honor.  
 24 From our perspective, Your Honor, we put forth the fact of  
 25 which certifications were out there. This is a challenge to try

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1 THE COURT: All right.  
 2 MR. RAUBICHECK: -- not only because it's an 11th hour  
 3 filing with which we were just served literally as we came in,  
 4 but also because what it is going to invite is it's going to  
 5 invite bringing a whole new party into this case and digging with  
 6 respect to facts that aren't even in the administrative record of  
 7 this case, because this issue wasn't raised by any party until  
 8 this afternoon.  
 9 FDA would be required to go back, if Your Honor wanted  
 10 more delving into this, find out what the administrative record  
 11 contains with respect to a whole separate ANDA, which is  
 12 Geneva's, and they're not even a party to this action.  
 13 It seems to me we ought to focus on the facts here.  
 14 That's Alphapharm's position.  
 15 THE COURT: Thank you.  
 16 MS. MAZZOCHI: And, Your Honor, if I may respond.  
 17 Part of the reason why we've been somewhat hampered in  
 18 this is because FDA does in fact keep all of the notice letters  
 19 confidential. They did not identify the companies who were  
 20 involved in this and we've been getting the record in dribs and  
 21 drabs. And as soon as we identified this as -- as soon as we  
 22 were able to identify that Geneva was in fact the company that  
 23 was at issue with respect to the '449 patent, which we only found  
 24 out in FDA's surreply brief, we immediately brought this to the  
 25 attention of the Court.

5 (Pages 14 to 17)

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1 And if I may, I'd like to explain in a bit more detail,  
2 first, as to why the present administrative record, as it  
3 currently stands, does in fact indicate that the '449 patent  
4 certification by Geneva is, in fact, not a paragraph IV  
5 certification that is proper. And I think that's critical  
6 because --

7 THE COURT: Well, forgive me for interrupting. Do you  
8 want to do that in support of this current motion for leave to  
9 file or do you want to do that in support of the previous motions  
10 filed?

11 MS. MAZZOCHI: Personally, Your Honor, I think that they  
12 both are essentially one and the same because --

13 THE COURT: Because I'm going to reserve ruling on this  
14 motion filed today.

15 MS. MAZZOCHI: Right.

16 THE COURT: So --

17 MS. MAZZOCHI: That I understand.

18 THE COURT: So your clock is still running. But go ahead.

19 MS. MAZZOCHI: That's fine.

20 The whole basis -- the whole rationale by FDA as to why  
21 they think they're entitled to award Alphapharm with final  
22 approval potentially tomorrow is because they said that  
23 Alphapharm is, in fact, one of the four companies that's allowed  
24 to engage in shared exclusivity status.

25 However, if in fact Alphapharm is not a first filer who

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1 The reason why can be found both at administrative record  
2 tab 23 as well as in Alphapharm's surreply; I believe it's  
3 Mr. Raubicheck's Exhibit A, attached to his declaration.

4 Exhibit A attached to his declaration indicates that  
5 Geneva believed that GSK was the owner of the '449 patent.  
6 That's not the case. The '449 patent is not owned by Glaxo and,  
7 under the statute, in order for notice of a paragraph IV  
8 certification to be effective -- and this is found at 21 U.S.C.  
9 355(j)(2)(B)(i)(I) -- the applicant is required to give "each  
10 owner of the patent which is the subject of the certification or  
11 the representative of such owner designated to receive such  
12 notice" proof that they have submitted -- or notice that they  
13 have submitted a paragraph IV certification.

14 And the reason why this is important is because if, in  
15 particular, validity issues are going to be involved in any  
16 patent challenge, you want to -- and someone is, you know, going  
17 to, in theory, obtain a benefit by sticking their neck out to go  
18 litigate, you want to make sure that the patent owner has been  
19 provided with notice so that they can potentially come into the  
20 fold.

21 Here, according to the notice letter that is attached to  
22 Mr. Raubicheck's declaration, Geneva only sent their paragraph IV  
23 notice to SmithKline. Tab 23 of the administrative record is a  
24 submission of the '449 patent to FDA. In that submission, it is  
25 the named inventor of the '449 patent, and I believe his name is

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1 has blocked somebody else -- i.e., Geneva -- then Alphapharm  
2 should not be awarded any shared exclusivity at all.

3 And if I may, Your Honor, I've prepared a couple of  
4 demonstrative exhibits just to explain why this is in fact the  
5 case. And if I may, I'd like to provide the Court with a copy.

6 The first illustration that I've provided you sort of goes  
7 through what FDA considers to be its mutual blocking scenario.  
8 And in particular, I would like to focus on the '449 patent.

9 Now, when FDA applies its shared exclusivity regime, what  
10 FDA does is it says: Who are all of the first filers? The next  
11 question that it asks is: Are these first filers blocking any  
12 other first filers? If they are, then FDA invites them into the  
13 fold and says, you know, we'll determine whether or not you can  
14 all share.

15 Here the only patent that Alphapharm has any first filer  
16 status for is the '449 patent. And FDA has taken the position  
17 that the 10, 20, and 30 milligram certification by Alphapharm is  
18 blocking Geneva; i.e., Company X. With respect to the 40  
19 milligram dosage, Zenith is blocking Alphapharm.

20 If we go to the next page, then we get to what we consider  
21 to be the blocking scenario, based on what facts are available in  
22 the administrative record. We believe that the administrative  
23 record does not support a showing that Geneva did, in fact,  
24 submit an appropriate paragraph IV certification with respect to  
25 the '449 patent.

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1 Dr. Norden, and his agent is also -- his agent or representative  
2 is also identified, and I believe his name is Jeffrey Oster.  
3 Neither of these people are affiliated or associated with  
4 GlaxoSmithKline.

5 So the fact that Geneva may have sent some notice to  
6 SmithKline is not capable of creating a true paragraph IV  
7 certification that is proper and perfected under the statute.

8 And the significance of this, of course, is clear because  
9 if -- well, hopefully I can make it clear -- because if Geneva  
10 has not, in fact, certified for the '449 patent, Alphapharm  
11 cannot block Geneva.

12 And Geneva was not even required to submit a paragraph IV  
13 certification for the '449 patent for the same reason that  
14 Torpharm was not required to submit a paragraph IV certification;  
15 namely, because that patent was late-listed.

16 So Geneva wasn't required to submit a paragraph IV  
17 certification for the '449 patent. To the extent they may have  
18 attempted it, it may not even be effective. Based on the  
19 administrative record, it appears to be wholly defective.

20 So if Geneva is out of the picture, then we get to the  
21 blocking scenario that's present on the record, as we graphically  
22 depict it here, which is that there is no first filer on the '449  
23 patent who is blocking anyone on the 10, 20, 30 milligram dosage  
24 forms.

25 To the extent that Zenith has prepared a 40 milligram

6 (Pages 18 to 21)

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1 first -- or has obtained a 40 milligram first filer status, the  
2 only person that they could be blocking would be Alphapharm, but  
3 Alphapharm is no longer part of the equation because Alphapharm  
4 doesn't have the true first filer status.

5 So what that ultimately means is that Alphapharm really  
6 does not have a seat at the table. Alphapharm should not have  
7 been entitled to any shared exclusivity in the first instance.

8 And in terms of, you know, which party is in the best  
9 position to determine this, in theory, this should have been FDA.

10 As to whether FDA actually did go back to -- or when it  
11 even awarded its shared exclusivity, whether FDA actually  
12 confirmed that Geneva did in fact submit a true and proper  
13 paragraph IV certification for the '449 patent, it appears that  
14 the agency did not, in fact, consider it. Or if there was a  
15 proper certification, evidence of that is not provided here in  
16 the administrative record.

17 And if I can just direct your attention to the next  
18 illustration that we provided you with, the only reason why FDA  
19 says that Alphapharm is entitled to shared exclusivity, despite  
20 the fact Alphapharm cannot block Torpharm, is because Alphapharm  
21 on the '449 patent was blocking Geneva, who in turn was blocking  
22 Torpharm.

23 If you take that arrow of the '449 patent out of the  
24 equation, Alphapharm does not mutually block anybody. And the  
25 entire purpose of the shared exclusivity regime, according to

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1 but even if it is to be followed, on the facts here, Alphapharm  
2 still is not entitled to any shared exclusivity and final  
3 approval of its ANDA should be postponed until on or about  
4 March 6th, 2004.

5 Thank you.

6 THE COURT: All right. Thank you.

7 Mr. Stearn, do you want to go first?

8 MR. STEARN: Yes, Your Honor. Thank you, Your Honor.

9 Your Honor, the facts on this record right now are that  
10 Torpharm filed first paragraph IV certifications with regard to  
11 certain patents and that others filed -- including Alphapharm --  
12 filed paragraph IV certifications as to other patents.

13 In our surreply brief, we put forward who were the first  
14 filers. It's not part of the administrative record because the  
15 applications by law of other applicants are not disclosed and  
16 it's not -- and furthermore, in the citizen petition process,  
17 this is not something that -- anything that was raised by  
18 Torpharm.

19 In fact, a lot of these arguments I'm hearing for the  
20 first time today. And it's entirely a new argument to say  
21 that -- to start challenging the paragraph IV certifications.

22 With regard to the law, the statute and the regulations,  
23 Your Honor, the statute, which we keep hearing is obvious, is not  
24 really made much reference to by Torpharm. What the statute  
25 actually says -- it actually regards when FDA approves.

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1 FDA, was to ensure that people who were mutually blocking each  
2 other, by sharing exclusivities, would no longer be mutually  
3 blocking each other. Here, if Alphapharm is not mutually  
4 blocking any of the other first filers, there's no reason for  
5 Alphapharm to share in any 180-day exclusivity period.

6 So -- I believe I'm getting close in my time, so if I may  
7 conclude, even if we wanted to accept the most far out  
8 permutation of FDA's view as to why shared exclusivity directly  
9 or indirectly applies to devalue Torpharm's 180-day exclusivity  
10 period here, the facts are simply not present on this record to  
11 permit final approval of Alphapharm's ANDA and certainly not for  
12 all of the approved doses.

13 And, Your Honor, I know that several of these arguments do  
14 involve some new permutations of the facts and for that I do  
15 apologize. Again, we are somewhat hampered by our own ability to  
16 gain access to the full administrative record before the FDA.

17 But ultimately, we believe that the law -- the first  
18 applicant approach is the proper one. To the extent there is to  
19 be any sort of equitable considerations or a patent-by-patent  
20 approach with respect to later-listed patents, we believe that  
21 the cascading approach is the only one that remains true to the  
22 spirit of Hatch-Waxman by actually providing the required  
23 incentive to go out and litigate and challenge later patents.

24 And with respect to the shared exclusivity regime that FDA  
25 has proposed, we believe that it is not supported by the statute,

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1 It does not grant this exclusivity right, which is  
2 indivisible; rather, where there is a certification and there's a  
3 previous certification regarding that patent, blocking applies.

4 Over and over again, the statute refers to these  
5 certifications as patent-specific. Specifically, the  
6 certifications are "to each patent" under 355(j)(2)(A)(vii). The  
7 certifications must state that, quote, "such patent," unquote, is  
8 not infringed. Further, the exclusivity trigger is by a decision  
9 on, quote, "the patent which is the subject of the  
10 certification."

11 All right. So by the actual words of the statute, the  
12 actual word of the statute require a patent-by-a-patent approach.

13 Further, the regulation, which is even more direct, states  
14 that where the application has a certification and there's a  
15 previously submitted application containing a certification,  
16 quote, "to the same patent," blocking applies.

17 Furthermore, the regulations actually define who is the  
18 first applicant by saying, quote, "the applicant submitting the  
19 first application," unquote, is the one that submits an  
20 application and where that application contains a certification  
21 to the specific patent at issue.

22 THE COURT: Well, that assumes that the regulation  
23 accurately and properly or permissibly interprets the statute, so  
24 go back to the statute.

25 MR. STEARN: I would be happy to go back to the statute,

7 (Pages 22 to 25)

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<p style="text-align: right;">Page 26</p> <p>1 Your Honor.</p> <p>2 And in that statute, if I may, the statute states "if the</p> <p>3 application contains a certification described in subclause (IV)</p> <p>4 of paragraph (2)(A)(vii)" -- and that's the case here for</p> <p>5 Torpharm's application as well as the other applicants, and it's</p> <p>6 for a drug --</p> <p>7 THE COURT: The application referred to in the language</p> <p>8 you had started to read from does not refer to Torpharm's</p> <p>9 application; it refers to subsequent applications.</p> <p>10 MR. STEARN: Right. Well, Your Honor, when it says the --</p> <p>11 it says -- it must be for a drug for which a previous application</p> <p>12 has been submitted --</p> <p>13 THE COURT: That's Torpharm.</p> <p>14 MR. STEARN: -- under this subsection containing such a</p> <p>15 certification.</p> <p>16 Torpharm's application contained such a certification at</p> <p>17 the time that they amended these paragraph IV certifications.</p> <p>18 THE COURT: Well, where does the statute say at the time</p> <p>19 it amended the paragraph IV certifications?</p> <p>20 MR. STEARN: Well, what the statute says is -- the statute</p> <p>21 says where there is an application containing such a</p> <p>22 certification, the application contain such a certification at</p> <p>23 the time that the certification is filed.</p> <p>24 THE COURT: Right.</p> <p>25 MR. STEARN: Is that clear? I just want to make sure I'm</p>	<p style="text-align: right;">Page 28</p> <p>1 late-listed patents?</p> <p>2 MR. STEARN: Well, Your Honor, when -- it does so</p> <p>3 because -- first of all, it requires -- it requires an</p> <p>4 approach -- every time that there's a certification, it requires</p> <p>5 the FDA to look at it because, as I said, it's patent-specific.</p> <p>6 So every certification must be looked at anew. And when</p> <p>7 there's an amendment -- that is, when there's a new paragraph IV</p> <p>8 certification that's made -- until they make that paragraph IV</p> <p>9 certification, Torpharm's application is not an application</p> <p>10 containing that certification.</p> <p>11 Is that -- am I making myself clear?</p> <p>12 THE COURT: I can't say I followed that one.</p> <p>13 MR. STEARN: Okay. Your Honor, the point of all those --</p> <p>14 that language that I've gone through over -- about all the</p> <p>15 "patent-specific" is this: It attaches to the patent itself.</p> <p>16 That is, the Court must consider each patent as it comes and each</p> <p>17 patent and whether or not there's been a previous certification</p> <p>18 to that patent.</p> <p>19 And, Your Honor, to the extent that this is unclear and to</p> <p>20 the extent that it's ambiguous, the agency's interpretation must</p> <p>21 govern.</p> <p>22 Now, Torpharm admits --</p> <p>23 THE COURT: Okay. But before you get there, show me where</p> <p>24 the statutory language makes clear some discussion about having</p> <p>25 to look at patent certifications that are made for later-filed</p>
<p style="text-align: right;">Page 27</p> <p>1 making myself clear.</p> <p>2 THE COURT: Well, that sounds like a different time</p> <p>3 reference from what you said a moment ago. I thought you were</p> <p>4 referring to a time in which Torpharm had filed amended paragraph</p> <p>5 IVs after Glaxo had submitted these eight or nine additional</p> <p>6 patents.</p> <p>7 MR. STEARN: Well, yes, Your Honor. With regard to those</p> <p>8 patent certifications, FDA's interpretation as well as the</p> <p>9 wording of the statute says that the statute is -- is that if the</p> <p>10 application contains a certification, okay -- which it does here;</p> <p>11 it's a certification; and it does for Torpharm -- and it's for a</p> <p>12 drug for which a previous application has been submitted</p> <p>13 containing such a certification.</p> <p>14 So the other applications -- for instance, Company X's, as</p> <p>15 we call it -- was a previous application containing that</p> <p>16 certification, because Torpharm's application only became such an</p> <p>17 application at the time that they amended this -- these --</p> <p>18 THE COURT: "They" who?</p> <p>19 MR. STEARN: Torpharm's application only became an</p> <p>20 application containing such a certification -- that is, these</p> <p>21 late-listed patents -- at the time that they amended their</p> <p>22 paragraph IV certification.</p> <p>23 THE COURT: Well, that's true, but where does this</p> <p>24 language of the statute narrow us to a time at which Torpharm has</p> <p>25 filed an amended ANDA to include certifications concerning the</p>	<p style="text-align: right;">Page 29</p> <p>1 patents.</p> <p>2 MR. STEARN: Okay. Well, Your Honor, I'd take exactly</p> <p>3 what it says in the statute itself. First, it says "if the</p> <p>4 application contains a certification." There's no time</p> <p>5 limitation on that. There's no -- it doesn't say "once this" --</p> <p>6 you know, the first certification. "When it contains a</p> <p>7 certification, describe."</p> <p>8 And the "describe" -- and what the reference is to each</p> <p>9 patent. So -- thus it requires the FDA to look at those amended</p> <p>10 certifications first, in the first instance, to determine whether</p> <p>11 there's --</p> <p>12 THE COURT: You keep saying "amended certifications."</p> <p>13 MR. STEARN: Well, I should say -- I shouldn't say</p> <p>14 "amended certifications," Your Honor. I should say "a new</p> <p>15 certification -- a new paragraph IV certification," which is a</p> <p>16 change in their application.</p> <p>17 THE COURT: Well, the statute, at the point from which you</p> <p>18 are beginning to read from it, says: "If the application</p> <p>19 contains a certification and is for a drug" -- and it goes on.</p> <p>20 MR. STEARN: Right.</p> <p>21 THE COURT: That application has to do with any ANDAs that</p> <p>22 come after someone else has filed an ANDA, correct?</p> <p>23 MR. STEARN: Well, Your Honor, it says -- I'm not sure I</p> <p>24 follow your question. Let me make sure I understand your</p> <p>25 question.</p>

8 (Pages 26 to 29)

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1 THE COURT: To complete the language, it says: "If the  
2 application -- if the application contains a certification and is  
3 for a drug for which a previous application has been submitted  
4 under this section containing such a certification" --  
5 MR. STEARN: Right.  
6 THE COURT: Now, that clause contains two different  
7 references to the word "application."  
8 MR. STEARN: Right.  
9 THE COURT: The first reference -- the second reference to  
10 the word application is modified by "previous."  
11 MR. STEARN: Right.  
12 THE COURT: The second reference to application -- namely,  
13 "previous application" -- must necessarily refer to one that had  
14 been filed earlier than the application referred to in the  
15 beginning of that quote, correct?  
16 MR. STEARN: Well, Your Honor, first, I'd say that  
17 "application" is also modified by the clause "containing such a  
18 certification."  
19 THE COURT: Assume that the previous application has a  
20 certification under paragraph IV for a patent.  
21 MR. STEARN: Right.  
22 THE COURT: The beginning of that clause, then, would be:  
23 "If the application," meaning a subsequent application, "contains  
24 a certification under paragraph IV for the patent."  
25 MR. STEARN: Right. That's correct.

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1 MR. STEARN: Correct.  
2 THE COURT: We won't name them, but other companies --  
3 Alphapharm and some other companies -- file ANDAs for Paroxetine  
4 afterwards.  
5 MR. STEARN: Yes.  
6 THE COURT: Right?  
7 MR. STEARN: Correct.  
8 THE COURT: Do those ANDAs that the other companies filed  
9 contain paragraph IV certifications about the '723 patent?  
10 MR. STEARN: Yes.  
11 THE COURT: All right. Of what significance is that?  
12 MR. STEARN: Well, the significance of that first part  
13 under our approach, Your Honor, is that for -- is that other  
14 applicants can be blocked -- or I should say the agency blocks  
15 the applications -- approval of these other applications that  
16 have been filed, okay.  
17 But what this case -- and I don't think anybody is saying  
18 anything different about the '723 patent.  
19 What this case is about at this point, Your Honor, I think  
20 is these other patents. And with these other patents -- that is,  
21 Company X files an application; that's an application; and with  
22 regard to that, the application of the statute -- the  
23 certifications are patent-specific -- those applications --  
24 there's previously filed applications containing the  
25 certification before Torpharm. That is, with regard to the other

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1 THE COURT: Okay.  
2 MR. STEARN: And, Your Honor, we submit that that is the  
3 case with Torpharm's -- with certain of Torpharm's  
4 certifications.  
5 THE COURT: Well, take the very first ANDA that it filed.  
6 MR. STEARN: Yes.  
7 THE COURT: It had a certification in that first -- in the  
8 ANDA that it filed --  
9 MR. STEARN: Yes.  
10 THE COURT: -- back in March of '98 --  
11 MR. STEARN: Yes.  
12 THE COURT: -- for the '723 patent.  
13 MR. STEARN: Yes. And by doing so, they had blocking  
14 rights -- or I should say there was a block of other applicants;  
15 but similarly, other applicants that filed the first paragraph IV  
16 certifications to other patents had the ability -- and that's  
17 what we call Company X and Company Y -- FDA was required to block  
18 Torpharm's application as well.  
19 THE COURT: Well, let's try to find where in the statute  
20 that result is required. And let's look at it in terms of the  
21 facts.  
22 Torpharm files its ANDA with a paragraph IV  
23 certification --  
24 MR. STEARN: Yes.  
25 THE COURT: -- for patent '723.

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1 patents that are at issue here, the '132 patent and so on.  
2 In other words, there are previous applications containing  
3 that certification that have been filed.  
4 Is that clear? At least our point, is that point clear?  
5 THE COURT: Go ahead.  
6 MR. STEARN: Your Honor, further, let me go on to the next  
7 point, which is that, to the extent it's ambiguous, the extent --  
8 whether or not this filing is an ambiguous term, then the Court  
9 must defer to FDA's interpretation and its regulation and --  
10 THE COURT: What if it's not?  
11 MR. STEARN: Well, Your Honor, if it's not ambiguous, the  
12 question is -- the Court must apply it?  
13 There's some restrictions in terms of the applications  
14 straightforwardly. For instance, if it produces an absurd  
15 result, which -- or, it's out -- the Court must consider other  
16 provisions of the statute in terms of whether or not those --  
17 that makes sense in terms of the statute.  
18 But yes, that's the first step, to look at the statute.  
19 We submit, Your Honor, that the interpretation that most closely  
20 follows is the one that is patent-specific that covers the  
21 patents.  
22 THE COURT: Torpharm has argued that the language is  
23 unambiguous and that it requires a first filer drug-specific  
24 approach. What is the result -- what is the absurd-result that  
25 flows from that argument?

9 (Pages 30 to 33)

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1 MR. STEARN: Well, Your Honor, I don't -- that's not -- I  
 2 wouldn't -- I would say that the problem that we have -- we have  
 3 multiple problems with that, but first is that by doing so, we  
 4 would say that it's not an unambiguous -- that's not an  
 5 unambiguous reading of the statute; in other words, that the  
 6 statute does not call for that because the statute repeatedly  
 7 refers to certifications as being specific. It says there's --  
 8 it requires, wherever there is "a certification."  
 9 And just as this Court applied "a court," whether it's a  
 10 District Court or an appellate court, "a certification" applies  
 11 wherever there is a certification. So we don't think that that  
 12 closely follows the statutory language.  
 13 We also would submit that it doesn't follow the overall  
 14 structure of Hatch-Waxman. And we put forward arguments about  
 15 that in our briefs, Your Honor, in that it does deprive  
 16 incentives of other applicants to file and challenge those  
 17 late-listed patents, in the sense that by limiting it to one  
 18 first applicant, it takes away an incentive to challenge those  
 19 late-listed patents, which we think is inconsistent with  
 20 Hatch-Waxman.  
 21 I would add with regard to the ambiguity of the statute,  
 22 Your Honor, this District Court, in Dr. Reddy's opinion, page 27,  
 23 did call this provision ambiguous. If I could quote from page  
 24 27, it says: "But considering section 355(j) as a whole, the  
 25 phrase, quote, 'a drug for which a previous application has been

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1 point this Court must address this question because we believe  
 2 that at some point, step 2 Chevron comes into account.  
 3 But FDA issued a regulation on this point. On this issue,  
 4 the regulation is patent specific, and further, it says FDA's  
 5 interpretation of its own regulation is entitled to substantial  
 6 deference under Auer and Bristol-Myers. Torpharm has never  
 7 responded to that argument.  
 8 Furthermore, case law, such as American Express versus  
 9 United States --  
 10 THE COURT REPORTER: I'm sorry. Please slow down.  
 11 MR. STEARN: Further, there's case law, including American  
 12 Express versus the United States, 262 F.3d 1376; the Barnhart  
 13 case, which is cited in our brief, makes clear that this  
 14 continues despite Christensen.  
 15 Secondly, Mead, contrary to what Torpharm has cited, does  
 16 not stand for the proposition that there must be rule making in  
 17 fact, to take out deference. It says: "Delegation of such  
 18 authority may be shown in a variety of ways, such as by an  
 19 agency's power to engage in adjudication," et cetera.  
 20 And FDA makes approval decisions in this case. The  
 21 standard -- there's a standard under Federal Election Commission  
 22 versus NRA, 254 F.3d 173, which is applicable in this circuit,  
 23 which says: "Where its actions are taken pursuant to a detailed  
 24 statutory procedure, fulfilling its statutory responsibilities  
 25 has the force of law. The agency is entitled to deference."

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1 submitted containing such certification,' unquote, is ambiguous."  
 2 That's the precedent I would submit to this Court.  
 3 Further --  
 4 THE COURT: Is it binding?  
 5 MR. STEARN: -- Your Honor, on page 28 --  
 6 THE COURT: Is it binding?  
 7 MR. STEARN: I think it's one of the exhibits to our --  
 8 THE COURT: Is that precedent binding on me?  
 9 MR. STEARN: Well, Your Honor, I believe that it is in the  
 10 sense that this is a question -- I mean, in terms of considering  
 11 whether or not there's a -- the issue in that case was whether  
 12 the ANDA contained a paragraph IV certification on a patent at  
 13 the time of FDA's exclusivity decision. So it was in terms of  
 14 the timing of the exclusivity decision. So it was trying to  
 15 determine this issue about -- that Your Honor is asking me about.  
 16 And further, on page 28 of that same decision, it says  
 17 quote "when certifications are added post-submission, comma, the  
 18 ANDA was not, quote, 'submitted containing,' unquote, them."  
 19 So in other words, the -- Dr. Reddy's decision on page 28  
 20 talks about the filing time of these certifications as -- filing  
 21 times with regard to the exclusivity determination as being the  
 22 time of the filing of the paragraph IV certifications.  
 23 Very briefly, Your Honor -- I think I'm about out of  
 24 time -- but I would just add, very briefly, with regard to  
 25 deference, first, FDA did, in fact -- and we believe that at some

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1 And finally, we believe the agency is entitled to Skidmore  
 2 deference.  
 3 With that, Your Honor, I think my time is up, but I'm  
 4 happy to respond to any questions the Court has.  
 5 THE COURT: All right. Thank you.  
 6 Mr. Raubicheck.  
 7 MR. RAUBICHECK: Thank you, Your Honor.  
 8 I'm going to try to focus on as many new points and not  
 9 repeat what other counsel have said, with the sole exception of  
 10 first addressing Your Honor's concern about the statutory  
 11 language.  
 12 If you focus on the statute that Your Honor was looking  
 13 at, 21 U.S.C. section 355(j)(5)(B)(iv), that is the 180-day  
 14 exclusivity provision in the statute. As Your Honor was pointing  
 15 out, the statute says: "If the application contains a  
 16 certification described in" -- and they refer to the  
 17 certification section of the statute -- "and is for a drug for  
 18 which a previous application has been submitted under this  
 19 section containing such a certification."  
 20 Just looking at those words, in Your Honor's example,  
 21 Torpharm, as the first ANDA applicant for Paroxetine, filed its  
 22 ANDA with a paragraph IV certification on the '723 patent. At  
 23 that point in time, Torpharm was first to file with respect to  
 24 the '723 patent.  
 25 THE COURT: And with respect to Paroxetine tablets.

10 (Pages 34 to 37)

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<p style="text-align: right;">Page 38</p> <p>1 MR. RAUBICHECK: And with respect to Paroxetine tablets.  2 THE COURT: Generic Paroxetine.  3 MR. RAUBICHECK: Generic Paroxetine. Correct. Correct.  4 But fortunately or unfortunately, this world of  5 certifications against listed Orange Book patents isn't static.  6 That particular event, the first filer's certification against  7 the first listed Orange Book patent —  8 THE COURT: The only listed Orange Book patent.  9 MR. RAUBICHECK: At the time. At the time.  10 THE COURT: Yeah.  11 MR. RAUBICHECK: Unfortunately, that situation is not  12 static. It changes over the course of time. In this particular  13 situation, SmithKline Beecham was able, subsequent to the listing  14 of the '732 patent, to obtain eight additional patents from the  15 U.S. Patent and Trademark office over a two-year span. And what  16 FDA — what the statute requires — now let's flip back to the  17 reference.  18 And "if the application contains a certification described  19 in subclause (IV) of paragraph (j)(2)(A)(vii)" — let's turn to  20 21 U.S.C. section 355(j)(2)(A)(vii); it says that "each ANDA must  21 contain a certification, in the opinion of the applicant and to  22 the best of his knowledge, with respect to each patent which  23 claims the listed drug or claims the use for which the applicant  24 is seeking approval, that such patent is invalid or will not be  25 infringed."</p>	<p style="text-align: right;">Page 40</p> <p>1 have to go back and amend your ANDA to certify against any newly  2 issued patent coming out of the PTO that is given to the FDA by  3 the brand that goes in the Orange Book.  4 THE COURT: But where in the statute does it say that  5 that, therefore, eliminates the first filer's status as a first  6 filer?  7 MR. RAUBICHECK: I'll tell you where it says that. If you  8 go back to the exclusivity language that we were talking about in  9 section 355(j)(5)(B)(iv): "If the application contains a  10 certification described in paragraph IV and is for a drug for  11 which a previous application has been submitted under this  12 section containing such a certification."  13 When Torpharm filed, they were the previous application  14 containing such a certification with respect to the patent that  15 was listed at the time, which was the '723 patent. Later on,  16 however, as the '449 patent and these other patents started  17 getting listed in the Orange Book, and as other applicants came  18 to file, it came to pass that Torpharm wasn't as quick on the  19 trigger as they could have been. In other words, they didn't  20 amend when those new patents got into the Orange Book right away.  21 For some inexplicable reason, they waited and these other  22 applicants got in there with their paragraph IV certifications  23 against these newly listed patents.  24 So that — let's just take the — another — patent X, for  25 example.</p>
<p style="text-align: right;">Page 39</p> <p>1 THE COURT: And which patents claimed the Paroxetine drug  2 when Torpharm filed its answer?  3 MR. RAUBICHECK: Just the '723. But thereafter — and  4 this has happened frequently over the course of Hatch-Waxman's  5 history — brand name companies, in order to prolong their  6 monopolies, keep getting new patents. That's part of the game.  7 They've wanted more 30-month stays. Congress just recently  8 stepped in to stop that and said you only get — now you only get  9 one 30-month stay.  10 But we're operating here under the former rules because  11 that's not retroactive.  12 SmithKline went ahead and got eight additional patents.  13 And the world wasn't static then either because you had  14 subsequent ANDA applicants like Alphapharm, like Geneva, like  15 Zenith that come along. And as they file their ANDAs, they had  16 to certify against whatever patents were in the Orange Book as of  17 the time they filed their subsequent paragraph IV applications.  18 THE COURT: Although isn't, really, Hatch-Waxman intended  19 to try to get these generic manufacturers to move as quickly as  20 they can to file?  21 MR. RAUBICHECK: Absolutely. But the statute slows them  22 down by "each patent" language. The statute basically says,  23 okay, if the patent owner gets another patent later on and your  24 application is still pending at FDA, because it usually takes  25 about two years to get ANDA approval, then the statute says you</p>	<p style="text-align: right;">Page 41</p> <p>1 THE COURT: But those companies, when they filed their  2 ANDAs, for them to be complete ANDA's worthy of consideration —  3 MR. RAUBICHECK: Right.  4 THE COURT: — they had to contain paragraph IV  5 certifications about the '723 patent.  6 MR. RAUBICHECK: Correct. But also against all the  7 others.  8 THE COURT: And that eliminates the fact that Torpharm had  9 filed before everybody else on the '723 patent?  10 MR. RAUBICHECK: No, it didn't eliminate that fact.  11 That's the whole purpose — that's the whole hangup FDA has had  12 with these mutually blocking exclusivities.  13 Because let's take patent — let's take a hypothetical  14 patent '123. My client Alphapharm comes along and,  15 hypothetically, let's say, we're the second filer. We file our  16 ANDA after Torpharm. We're second on the '723 patent, but when  17 we file our ANDA, we see that there's the '123 patent in there as  18 well as the '723, so we have to certify against both.  19 Torpharm could have certified against the '123 because it  20 was in the Orange Book for a while, but for some reason, they  21 didn't. They didn't amend, as the statute requires them to  22 certify against each patent. And so on the '123 patent —  23 THE COURT: Well, they didn't do it then.  24 MR. RAUBICHECK: — Alphapharm became —  25 I'm sorry, Your Honor.</p>

11 (Pages 38 to 41)

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1 THE COURT: They didn't do it then.

2 MR. RAUBICHECK: Correct. Or before then. Or before

3 then.  
4 Under my example, Alphapharm's '123 application becomes  
5 the previous application with a certification on the '123 patent.  
6 And when Torpharm gets around to amending and filing, then  
7 Torpharm is the subsequent application as to that patent. That's  
8 the way the system works. That's the way FDA has been  
9 interpreting it for ten years.

10 This patent-by-patent exclusivity regulation which spells  
11 this out was part of the final ANDA regulations promulgated in  
12 1994 and industry and FDA have been operating under this for some  
13 time.

14 THE COURT: Well, you're right. Did --

15 MR. RAUBICHECK: And nobody until this case -- because  
16 let's be clear what Torpharm really wants here. They're  
17 basically saying, we're making 265 million dollars off our  
18 180-day exclusivity, according to their own papers. We want it  
19 all. We think we should have it all, even though we weren't  
20 first to file on at least four or five subsequently listed  
21 patents in the Orange Book. And these other guys should get  
22 nothing.

23 And what they're really fighting for is to be the sole  
24 generic applicant into the marketplace for the full 180 days.  
25 But according to the record, since September 8th, when they went

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1 on the market, they've made 170 million dollars off this drug in  
2 sales.

3 But -- so what they're trying to do is not only get that  
4 extra 50 million bucks, but they're trying to take down with them  
5 the whole patent-by-patent exclusivity regulation and scheme that  
6 FDA set up ten years ago and they're trying to vitiate the whole  
7 shared exclusivity principle that FDA derived from that scheme  
8 when you have situations -- and this is the fourth one that's  
9 occurred in the last three or so years -- they're trying to tear  
10 that whole thing down just so they can get the extra 50 million  
11 bucks.

12 And we -- you know, basically, it's our position, as is  
13 the FDA's, that the patent-by-patent scheme is inherent in the  
14 statutory language of "each patent" -- and the patent in the two  
15 sections we've been talking about.

16 And if the first filer isn't the first to file on all, as  
17 a matter of point in time, then that first filer becomes a  
18 subsequent filer on subsequently issued patents on which it slept  
19 on its opportunity, because these -- the brand company puts these  
20 into FDA; they go into the Orange Book as soon as they come out  
21 of the PTO.

22 If Torpharm had wanted to be first, they knew what FDA's  
23 interpretation was. As a matter of fact, and I'll point this out  
24 because Your Honor mentioned it in the gabapentin litigation  
25 that's in the D.C. circuit, in which one of my clients is

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1 litigating against the same Torpharm.

2 THE COURT: What case did you cite?

3 MR. RAUBICHECK: It involves the drug gabapentin and the  
4 name of the case is Purepac and Torpharm versus -- Purepac and  
5 Torpharm versus FDA. They're consolidated actions.

6 In that case, Torpharm is taking the position we want a  
7 share of exclusivity. That case was argued -- I argued that case  
8 in this very building at the end of November and we're waiting  
9 for a decision. It doesn't involve the validity of the shared  
10 exclusivity principle, but that's what they're after in that case  
11 because in that case, they say we're first to file on one patent;  
12 these other guys are first to file on another. We should get a  
13 share of the exclusivity.

14 Now they're here before this Court and saying we should  
15 get it all because of this interpretation of the statute that  
16 seeks to supplant what FDA has already decided. If you go to the  
17 July 30th decision, where FDA takes eight to nine pages to spell  
18 out for each of the applicants what the shared exclusivity  
19 principle is in the mutually blocking context, which it did in  
20 the Omeprazole situation a couple years ago, which it did in the  
21 Cisplatin situation back in 1999, basically, FDA said the way the  
22 statute reads, we have two choices: We can either do the  
23 one-first-applicant approach that Torpharm advocates or we could  
24 adopt a shared exclusivity approach, whereby we will award each  
25 first filer when there are multiple patents that are listed and

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1 different first filers.

2 And FDA made the choice that it would be more consistent  
3 with the language of these statutes that are before you to adopt  
4 a shared exclusivity approach. And as I'm sure Your Honor is  
5 well aware, the Federal Courts will not disturb a rational choice  
6 of an administrative agency if that choice is made under a  
7 permissible construction of the statute.

8 You know, it's like going back to the old -- one of the  
9 early FDA cases, actually, that was ever decided back in 1943 by  
10 the U.S. Supreme Court. The industry wanted it one way; FDA  
11 interpreted this particular statutory provision another way. The  
12 Quaker Oats case; it's cited in our brief.

13 The high court said look, the company might be right.  
14 Their interpretation might be reasonable under the statute. But  
15 that's not the issue. The issue is whether the agency made a  
16 permissible choice. And if so, the agency must be sustained.

17 This cascading approach that has been advanced, Your  
18 Honor -- it's a red herring. FDA never even considered it. It's  
19 not in the administrative record. This is something -- you want  
20 to talk about invention, Torpharm made it up in their brief. It  
21 doesn't deserve any consideration.

22 The question is: Is the FDA's interpretation rational?

23 THE COURT: Well, that's the second question.

24 MR. RAUBICHECK: What's the first?

25 THE COURT: What should it be under Chevron?

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1 MR. RAUBICHECK: Well, under Chevron, yes. What should it  
2 about under Chevron?

3 If the Court thinks that the statute is so clear that a  
4 one-first-all-applicant approach is the only way to read the  
5 statute, obviously, that's a matter of statutory construction for  
6 the Court.

7 If, however, the Court believes that the statute is silent  
8 or ambiguous on this point, then Chevron 2 comes into play, the  
9 Mead case comes into play, the Barnhart case comes into play and  
10 you must look at whether it's a permissible construction.

11 Now, one thing that I need to add, and I realize I'm  
12 running out of time, but I should still address. Your Honor has  
13 a motion. The motion effectively was argued by counsel so, it  
14 seems to me, we ought to get the opportunity to speak.

15 What they have said is, in going through the surreply  
16 briefs, this '449 patent that Alphapharm blocks Geneva on -- they  
17 say it doesn't really block Geneva because the notice of Geneva's  
18 paragraph IV certification was sent to the wrong guy. That's  
19 what they're saying. It wasn't sent to each owner of the patent.

20 I don't even know what the truth of that allegation is  
21 because we don't have FDA's administrative record on what Geneva  
22 filed and who they sent it to. The piece of paper that I put in  
23 as Exhibit A to my supplemental declaration was Geneva's notice  
24 letter on the '449 patent and other Paroxetine patents that  
25 Geneva attached to its complaint against Alphapharm in an

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1 MS. MAZZOCHI: Your Honor, if I may briefly respond on a  
2 few points.

3 First, with respect to the gabapentin situation, I would  
4 like to note that Judge Huvelle did, in fact, suggest that Apotex  
5 pursue a shared exclusivity claim in connection with the patents  
6 that were at issue. I further believe that under the first  
7 applicant approach in that case, had it been applied, we would  
8 have already triggered Purepac's exclusivity by now and could, in  
9 fact, have been on the market. As it stands right now under  
10 FDA's patent-by-patent approach, we are being kept off the  
11 market.

12 With respect to the statute itself, because we believe  
13 that -- we agree with Your Honor that if you start with the  
14 statute, in 355(j)(5)(B)(iv), the clause begins: "If the  
15 application contains a certification." And the certification is  
16 described in subclause (IV) of paragraph (2)(A)(vii).

17 Section (vii) states that the certification that is at  
18 issue is the one that includes the -- that -- with respect to  
19 each patent which claims the listed drug referred to in  
20 clause (i) is the one that is at issue. And when you look back  
21 at clause (i), that says "an abbreviated application for a new  
22 drug shall contain information to show that the conditions of  
23 use," et cetera, et cetera, "have been previously approved."

24 To Torpharm, that indicates that it is the application  
25 which matters.

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1 infringement case that they sued against -- against my client.

2 And it's still ongoing so it's a matter of public record.

3 We wanted to give the Court everything we had on the '449  
4 patent. But that's not what really is important here. It's not  
5 when the notice was sent to the patent owner and the ANDA holder.  
6 The issue is: Did Alphapharm file its paragraph IV certification  
7 with FDA before Geneva filed its paragraph IV certification with  
8 FDA? The filing of the notice with FDA is what's at issue, not  
9 when they sent the notice to the patent owner and ANDA holder.

10 What we're concerned about is: Who was first to file with  
11 FDA? And it's clear on the record that Alphapharm beats Geneva  
12 by about two years on that patent. So this, again, is a red  
13 herring.

14 Now, counsel may argue, well, under -- you really have to  
15 perfect the notice by filing -- perfect the certification by  
16 filing the notice, but that -- they did perfect it. They did  
17 send the notice. Now they want to attack the guys whom they sent  
18 it to.

19 But that doesn't change the basic fact of when it was  
20 filed with FDA. Filing a paragraph IV certification with FDA as  
21 part of your ANDA is the critical line of demarcation here; it's  
22 the critical standard. We beat them by two years.

23 That's all the court needs to know on that.

24 Thank you very much.

25 THE COURT: All right. Thank you.

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1 And furthermore, going back to section (j)(5)(B)(iv), if  
2 we are looking at when the later application shall be made  
3 effective, because we are not dealing with a court decision here,  
4 but we are dealing with the date of commercial marketing,  
5 subclause (I) states that "the application shall be made  
6 effective not earlier than the date the secretary receives notice  
7 from the applicant under the previous application."

8 So that, too, indicates that we should be concerned with  
9 an application-by-application basis, not a patent-by-patent  
10 basis. And if we are dealing with an application issue, then  
11 this is Chevron step 1 and the Court is entitled to order FDA to  
12 not approve Alphapharm's ANDA.

13 And that is true -- the Court doesn't even have to decide  
14 whether it wishes to adopt the one-first-applicant approach or  
15 whether Torpharm's cascading approach merits consideration in  
16 order to conclude that Alphapharm should not be entitled to  
17 secure final FDA approval under a shared exclusivity regime.

18 The other point I would like to address that FDA raised  
19 which -- is the question of: Is having a shared exclusivity  
20 regime one that meets the policy goals of Hatch-Waxman?

21 We contend that under the facts here, it certainly does  
22 not. As we've seen here today, when you have the shared  
23 exclusivity regime, FDA may not even reveal who is the first  
24 filer of an ANDA that is entitled to an exclusivity period. If  
25 you're another generic, not even necessarily a first filer

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1 operating in the marketplace, you're not even going to know who  
2 you should try to go after, perhaps, if you want to trigger their  
3 exclusivity by getting an early court decision of your own on one  
4 of the relevant patents.

5 If you follow the one-first-applicant approach, there's  
6 one applicant, a fixed number of patents and everyone in the  
7 industry can figure out who they should be targeting if they want  
8 to try to trigger their exclusivity period and which are the  
9 patents that are at issue, because that is going to be readily  
10 ascertainable and fixed in time.

11 So if FDA's goal is to ensure that there are not -- that  
12 an -- that a 180-day exclusivity period does, in fact, eventually  
13 get triggered so that other people can get on the marketplace --  
14 other generics can get on the marketplace, having multiple  
15 parties with exclusivity rights that the market can't even figure  
16 out until -- you know, here we are five years after we filed our  
17 first ANDA in 1998 and it wasn't until FDA's surreply brief that  
18 we finally figured out who had exclusivity rights assigned to  
19 whom -- you know, if you have a one-first-applicant approach, you  
20 at least know who to go after with respect to --

21 THE COURT: Well, if you're making a policy argument, how  
22 can you argue that having four generic manufacturers with some  
23 ability to put out on the market during an exclusive 180-day  
24 period as opposed to just one doesn't advance the Hatch-Waxman  
25 goals of getting as many generic -- cheaper generic drugs in the

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1 out there and challenge patents will be markedly diminished.

2 THE COURT: Can I just ask you: It's a bit of a tangent,  
3 but if the FDA shared exclusivity later ruling was issued in  
4 July, why did Torpharm wait until November 11th to sue?

5 MS. MAZZOCHI: We filed a citizen's petition with FDA  
6 asking them to reconsider their ruling and we raised many of the  
7 issues that we presented to the Court in its briefing.

8 We spoke with FDA, who had indicated that they were not  
9 planning on issuing final approval to anyone -- we actually told  
10 FDA that we would be suing earlier; they asked us to wait, on the  
11 grounds that there was not going to be anyone receiving final  
12 approval, so that they could give due consideration to our  
13 citizen's petition, which they declined to take action on. And  
14 the parties then entered into the present briefing schedule.

15 Thank you, Your Honor.

16 THE COURT: All right. Thank you.

17 I'm prepared to rule at this point. And I want to first  
18 recite the facts that I think are most important in coming to a  
19 decision here.

20 On December 29th of 1992, the FDA approved Glaxo's new  
21 drug application for Paxil. And at the time, Glaxo submitted  
22 information only on one patent which was listed in the Orange  
23 Book, referred to as patent '723 for Paroxetine.

24 In March -- on March 31st of 1998, Torpharm submitted its  
25 abbreviated new drug application for four dosage strengths of

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1 market as fast as possible?

2 MS. MAZZOCHI: I think there are two answers to that  
3 response. First, I think that the sooner the 180-day exclusivity  
4 period is triggered, the sooner everybody can get on the market.  
5 It wouldn't even necessarily be limited to just four individuals.

6 Second of all, the more people who get put into the  
7 exclusivity pie creates a disincentive to undertake the  
8 litigation costs associated with being a first filer. To provide  
9 a hypothetical, Apotex -- or Torpharm, rather, was the first to  
10 certify to the '723 patent. Let's assume that there was only one  
11 additional patent that was listed in the Orange Book and all of  
12 the pending ANDA applicants certified to it on the same day.

13 Under FDA's current regime, all of those ANDA applicants  
14 would be entitled to shared exclusivity, so even if Apotex would  
15 have done everything right and gotten everything on file  
16 immediately the day that a new patent was listed in the Orange  
17 Book, what would have been a full exclusivity right for Torpharm  
18 would now have been completely eliminated and would become no  
19 exclusivity right at all.

20 And when you are dealing with major blockbuster drugs,  
21 where the name brand drug companies fight extraordinarily hard  
22 over five years -- and longer in our situation here with  
23 Paroxetine Hydrochloride -- to try to maintain their own market  
24 monopoly, I think that Apotex -- or Torpharm -- sorry, late in  
25 the day -- Torpharm believes that the incentive to actually go

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1 generic Paroxetine tablets. It included a paragraph IV  
2 certification concerning the sole patent then listed in the  
3 Orange Book in connection with Paxil -- that's P-A-X-I-L -- the  
4 '723 patent.

5 Glaxo sued Torpharm for infringement soon thereafter, but  
6 lost. Beginning in March of 1999, Glaxo began to list, within 30  
7 days of their issuance by the Patent and Trademark Office, eight  
8 additional patents in the Orange Book regarding Paxil.

9 And that triggered the obligation of existing and new  
10 ANDA -- that's A-N-D-A -- applicants for generic Paroxetine --  
11 and that, I think, is P-A-R-O-X-E-T-I-N-E -- to file paragraph IV  
12 certifications concerning the added patents.

13 Torpharm did so at various different times.

14 On October 6th, 1999, Alphapharm filed its ANDA for  
15 Paroxetine tablets. Two other companies also filed Paroxetine  
16 ANDAs and all three ANDAs included paragraph IV certifications  
17 for the '723 patent among the other patent certifications. Some  
18 of these three competitors filed certifications concerning some  
19 of the eight new patents before Torpharm did.

20 On November 19th, 1999, Glaxo also listed late one patent,  
21 the '449 patent, that had been issued 15 months earlier in August  
22 of 1998. The existing applicants did not have to file paragraph  
23 IV certifications concerning the late-filed '449 patent. While  
24 some applicants did, Torpharm did not.

25 On July 30th, 2003, the FDA issued its final approval of

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1 Torpharm's ANDA and Torpharm began to sell its product on  
2 September 8th, 2003, claiming an exclusive right to have no other  
3 Paroxetine ANDA approved for 180 days; namely, until about  
4 March 6th, 2004.

5 Also on July 30th, 2003, however, the FDA granted shared  
6 exclusivity to three other Paroxetine ANDA applicants who had  
7 filed paragraph IV certifications concerning some of Glaxo's  
8 added nine patents before Torpharm did.

9 The FDA expects for Alphapharm's ANDA to be eligible for  
10 final approval on January 3rd, 2004 and Alphapharm asserts its  
11 right to sell its generic product on that date under the FDA's  
12 shared exclusivity ruling.

13 Now, it seems to me that there is no genuine dispute about  
14 these material facts and we can turn to whether either side is  
15 entitled to a judgment as a matter of law.

16 Torpharm's first claim for relief asserts that the FDA  
17 violated the Food, Drug and Cosmetics Act and the Administrative  
18 Procedure Act by awarding shared exclusivity to the three other  
19 ANDA applicants that certified first to subsequently listed  
20 patents, but certified after Torpharm did to the '723 patent.

21 It seeks, among other things, a declaration of its right  
22 to a fully exclusive 180-day marketing period and an injunction  
23 against the FDA granting final approval of Alphapharm's or anyone  
24 else's ANDA for immediate sale of Paroxetine tablets until after  
25 that 180-day period expires.

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1 This language may be thick, but in my judgment, it is not  
2 ambiguous. Applying the facts here to the statutory language,  
3 Torpharm filed its ANDA in 1998. It provided a paragraph IV  
4 certification regarding the '723 patent. That was the only  
5 patent listed in the Orange Book for this drug. At the time,  
6 there were no other paragraph IV certifications needed to compete  
7 Torpharm's paragraph IV certification requirements.

8 Torpharm was then a first filer for the drug product and a  
9 first filer on the '723 patent. It was Glaxo, the brand name  
10 manufacturer, that was then seeking to keep this generic  
11 competitor off the market, that shortly thereafter began  
12 submitting for listing in the Orange Book a series of additional  
13 patents that the FDA says created the prospect of exclusivity  
14 standoff.

15 It would be ironic if Congress meant to give the drug  
16 innovators such power when its aim was to get more and cheaper  
17 generics on the market faster.

18 Torpharm, therefore, responded to the incentive that  
19 Congress crafted. It moved before all the others and filed to  
20 take advantage of that exclusive 180-day marketing period for the  
21 generic drug.

22 The other three filed after Torpharm did. All filed for  
23 the same drug. All contained the same certifications regarding  
24 the '723 patent that Torpharm filed.

25 .. Nothing in the language of the statute undermines

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1 Under the APA, whether the FDA's letter ruling was not in  
2 accordance with the law is subject to Chevron analysis. If the  
3 language of the governing statute speaks unambiguously to the  
4 issue in question, the only question is whether the agency has  
5 given effect to Congress's clear command; if the statutory  
6 language is ambiguous, then the Court must give deference to any  
7 reasonable construction of the language by the enforcing agency.

8 In this case, there are two principal statutory provisions  
9 at issue. The first defines what a paragraph IV certification  
10 must be. It is, quote: "A certification, in the opinion of the  
11 applicant with respect to each patent which claims the listed  
12 drug for which the applicant is seeking approval, that such  
13 patent will not be infringed by the manufacture, use or sale of  
14 the new drug for which the application is submitted." That  
15 language is found at 21 U.S. Code section 355(j)(2)(A)(vii)(IV).

16 The second statutory provision is found at 21 U.S. Code  
17 355(j)(5)(B)(iv), which provides a 180-day exclusivity for the  
18 first applicant. The pertinent language says about subsequent  
19 applications that: "If the application contains a certification  
20 and is for a drug for which a previous application has been  
21 submitted under this subsection containing such a certification,  
22 the application shall be made effective not earlier than 180 days  
23 after the date the secretary receives notice from the applicant  
24 under the previous application of first commercial marketing of  
25 the drug under the previous application."

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1 Torpharm's status as the previous applicant, entitled to the  
2 exclusivity whenever the innovator lists new patents before the  
3 first ANDA is approved, that subsequent filers might certify on  
4 before the previous applicant does.

5 The plain language of the statute grants one first  
6 applicant exclusivity in marketing the new generic drug. It  
7 seems from the FDA's opposition brief that the FDA may have first  
8 abandoned the 1999 one-first-applicant proposed regulation  
9 because of negative comments received, not because the proposal  
10 was not faithful to the command of the statute.

11 But nevertheless, the FDA next abandoned the  
12 one-first-applicant approach in 2001, based upon its reading of  
13 the language not of the statute, but of its own implementing  
14 regulation. That reading created the principle that eligibility  
15 for exclusivity is based upon the particular patent at issue and  
16 not the drug product as a whole.

17 And I'm not even sure that the language of its own  
18 regulation mandates that principle, particularly if you integrate  
19 it with the facts here.

20 If you do that, the regulations would read: If Alpha's  
21 abbreviated new drug application contains a certification that  
22 the '723 patent will not be infringed and the application is for  
23 a generic copy of the same Paroxetine drug for which Torpharm's  
24 substantially completed abbreviated new drug application was  
25 previously submitted containing a certification that the '723

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1 patent would not be infringed, approval of Alphapharm's  
2 abbreviated new drug application will be made effective no sooner  
3 than 180 days from the date Torpharm first commences commercial  
4 marketing of its Paroxetine tablets."

5 In any event, even giving due deference to the agency's  
6 interpretation of its own regulation, as I must, what is key is  
7 whether the FDA has given effect to the clear command of the  
8 statute, not its own regulation.

9 All of the regulatory discussion about a patent-based  
10 approach and exclusivity standoff seems to have sprung from the  
11 regulators being enmeshed in the consequences of their  
12 interpretation of the regulation, rather than the plain language  
13 of the statute.

14 I reach my conclusion wholly independent of the fact that  
15 Congress last month amended the statute to make explicit the  
16 product-based approach for the 180-day exclusivity period.

17 The FDA argues in its opposition brief that the fact that  
18 the amendment added new protections from the potential abuses of  
19 a product-based system confirms that the FDA had appropriately  
20 construed the previous version of the statute.

21 It might be quite the contrary. It may suggest that the  
22 FDA previously got it wrong, although the FDA's concerns about a  
23 product-based system did warrant some statutory fixing.

24 In conclusion then, Torpharm is entitled to a declaration  
25 that the FDA acted contrary to the plain language of Section

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1 very least, by Monday.

2 THE COURT: All right. Let me ask that you do that.

3 And let me ask opposing counsel to look carefully at the  
4 draft and provide any feedback that you think might be warranted  
5 to the drafting counsel so that that can be filed as soon as  
6 possible to have a written memorialization of my oral ruling.

7 All right. Thank you very much, counsel, and good  
8 arguments. I appreciate hearing from all of you. Thank you for  
9 coming in.

10 You may be excused.

11 (Proceedings adjourned at 4:06 p.m.)  
12  
13  
14  
15

# 16 CERTIFICATE

17 I, Scott L. Wallace, RDR-CRR, certify that the  
18 foregoing is a correct transcript from the record of proceedings  
19 in the above-entitled matter.  
20

21 Scott L. Wallace, RDR, CRR  
22 Official Court Reporter  
23  
24  
25

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1 355(j)(5)(B)(iv) by awarding it shared exclusivity with three  
2 other subsequent ANDA applicants rather than a sole exclusive  
3 180-day marketing period for its generic Paroxetine tablets.

4 Torpharm is also entitled to an injunction against the FDA  
5 that preserves the status quo by barring the FDA from granting  
6 final approval of Alphapharm's or anyone else's ANDA for  
7 immediate sale of Paroxetine tablets until after Torpharm's  
8 180-day exclusive period expires.

9 I will enter judgment in favor of Torpharm on the first  
10 claim of its amended complaint.

11 Because the relief I am granting on the first claim of its  
12 amended complaint is, in effect, equal to or broader than the  
13 relief sought on the second and third claims of the amended  
14 complaint, I will dismiss those claims as moot.

15 This order is effective immediately, but I will ask  
16 Torpharm to draft a final written order consistent with this  
17 ruling and share it with opposing counsel for comment and joint  
18 revision, if any revision is needed, and then file it with the  
19 Court so there can be a written version of this oral order.

20 Let me ask counsel for Torpharm how quickly you think you  
21 can do that?

22 MS. MAZZOCHI: We'll do it tonight.

23 THE COURT: I can't hear you. Come up to the mike.

24 MS. MAZZOCHI: I apologize. We will try to circulate a  
25 draft to opposing counsel by the end of the day today or, at the

16 (Pages 58 to 60)